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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/579,529

03/06/2007

William G. Cance

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2999

21874

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07/01/2009

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EXAMINER

HOLLERAN, ANNE L

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/579,529	<b>Applicant(s)</b> CANCE ET AL.	
	<b>Examiner</b> ANNE L. HOLLERAN	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.  
4a) Of the above claim(s) 4,5,12-17 and 23-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,6-11 and 18-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/06</u> . | 6) <input type="checkbox"/> Other: ____.  |

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## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group I, species peptide of SEQ ID NO: 1, in the reply filed on March 27, 2009 is acknowledged. The traversal is on the ground(s) that no undue burden is placed on the Office in search the groups beyond that incurred by searching one or the other separately. This is not found persuasive because the restriction is required under 35 U.S.C. 121 and 372, where the restriction is based on a showing of a lack of unity of invention, and does not also require that there be a burden of examination. In the present case, applicants have not provided any arguments for why there is unity of invention between the different groups set forth in the requirement for restriction. However, it is noted that because each of the separate groups comprises its own technical feature, that the search and examination of each of the groups is not coextensive, an undue burden would be placed on the examiner to have to search and examine all four of the invention groups together because the search and examination of the different groups is not coextensive.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-47 are pending.

Claims 4, 5, 12-17 and 23-47, drawn to non-elected inventions, are withdrawn from consideration.

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 6-11, and 18-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis for this rejection is that the disclosure of the specification does not provide adequate support for the genus of agents that specifically bind focal adhesion kinase and induce apoptosis, or for compositions comprising fragments, variants or derivatives of SEQ ID NO: 1.

For a claim drawn to a genus, the written description requirement may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant, identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A “representative number of species” means that the species, which are adequately described, are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus (see Official Gazette 1241 OG 174, January 30, 2001).

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Claim 1 is broadly drawn to agents with the functional description that such agents bind focal adhesion kinase and induce apoptosis. Claims 6-11 and 18-22 encompass compositions comprising peptides, where the peptides may be those that are fragments, derivatives or variants of SEQ ID NO: 1.

The specification provides the teaching of SEQ ID NO: 1 or SEQ ID NO: 3, which appear to be peptides that are unrelated structurally because a search of SEQ ID NO: 1 does not provide documents teaching SEQ ID NO: 3. Therefore, there does not appear to be a correlation between the particular amino acid sequence of either SEQ ID NO: 1 or SEQ ID NO: 3 that correlates with the functions of binding to focal adhesion kinase and the induction of apoptosis. Therefore, one of skill in the art cannot use the teachings of SEQ ID NO: 1 or SEQ ID NO: 3 to envision the structures of fragments, variants or derivatives that will be peptides that bind to focal adhesion kinase and also induce apoptosis. The specification does not provide working examples of variants or fragments or a discussion of critical residues that are necessary for binding to focal adhesion kinase and the induction of apoptosis. Therefore, the specification fails to provide an adequate disclosure to support the breadth of the claimed agents or compositions.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Hungerford

(Hungerford, J.E., et al., The Journal of Cell Biology, 135(5): 1383-1390, 1996; cited in the restriction requirement).

Hungerford teaches separately a peptide and an antibody that each binds to focal adhesion kinase and causes cell to undergo apoptosis (see abstract; pages 1384-1386).

Therefore, Hungerford teaches an agent that is the same as that claimed.

Claims 1, 2, 6-11, 18, and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Sauk (US 7,361,730; Apr., 22, 2008; effective filing date Mar. 15, 1999).

Sauk teaches a peptide that has the same sequence as that of SEQ ID NO: 1 (see alignment). Sauk teaches fusion proteins where the protein is fused to a domain that allows peptide internalization or targeting. Sauk teaches fusion to an antibody (see column 5, line 61 - column 13, line 3). Therefore, Sauk teaches an agent or a composition that is the same as that claimed.

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US-09-936-565-3
; Sequence 3, Application US/09936565
; Patent No. 7361730
; GENERAL INFORMATION:
; APPLICANT: UNIVERSITY OF MARYLAND, BALTIMORE
; TITLE OF INVENTION: SURFACE LOCALIZED COLLIGIN/Hsp47 IN CARCINOMA CELLS
; FILE REFERENCE: UNIMD-4 WO
; CURRENT APPLICATION NUMBER: US/09/936,565
; CURRENT FILING DATE: 2002-02-04
; PRIOR APPLICATION NUMBER: 60/124,481
; PRIOR FILING DATE: 1999-03-15
; NUMBER OF SEQ ID NOS: 68
; SOFTWARE: PatentIn Ver. 2.1
; SEQ ID NO 3
; LENGTH: 12
; TYPE: PRT
; ORGANISM: Artificial Sequence
; FEATURE:
; OTHER INFORMATION: Description of Artificial Sequence: Synthetic
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; OTHER INFORMATION: peptide  
US-09-936-565-3

Query Match 100.0%; Score 89; DB 3; Length 12;  
Best Local Similarity 100.0%; Pred. No. 1.4e-05;  
Matches 12; Conservative 0; Mismatches 0; Indels 0; Gaps 0;  
Qy 1 WHWQWTPWSIQP 12  
| | | | | | | | | |  
Db 1 WHWQWTPWSIQP 12

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 6-11 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sauk (*supra*) in view of Bermudes (US 6,962,696; issue Nov. 8, 2005; effective filing date 10/4/1999).

Sauk teaches a peptide that comprises the same amino acid sequence as that of SEQ ID NO: 1 of the instant application. Sauk teaches fusion of peptides with other proteins for the purpose of targeting or cell internalization. Sauk fails to teach the use of HIV TAT protein. However, Bermudes teaches the use of TAT to enable internalization of polypeptides (see for example 81, line 1- column 82, line 45; see column 13, lines 1 -28). Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Sauk with those of Bermudes to make the claimed inventions, where the fusion partner is a protein such as HIV TAT domain. One would have been motivated by the teachings of Bermudes that TAT is useful for creating peptides that may be internalized by tumor cells for the purpose of treating cancer.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If



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attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran  
Patent Examiner  
June 22, 2009  
/Alana M. Harris, Ph.D./  
Primary Examiner, Art Unit 1643